DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 8 1997

Kathleen A. Dodson
Director of Congressional and Regulatory Affairs
American Orthotic and Prosthetic Association
1650 King Street, Suite 500
Alexandria, VA 22037

RE: 92P-0173/CP1

Dear Ms. Dodson:

This letter is in response to your Citizen Petition, dated April 10, 1992, on behalf of the American Orthotic and Prosthetic Association, requesting the Food and Drug Administration (FDA) to revoke the classification of external assembled lower limb prosthesis (21 CFR 890.3500). Separately, in a letter dated February 27, 1996, you requested, as an alternative that FDA reclassify the external assembled lower limb prosthesis from class II (special controls) into class I (general controls) and exempt the device from the premarket notification requirements. In accordance with 21 CFR 10.30(e)(2)(I), FDA is granting your amended petition of February 27, 1996 and intends to propose in the near future to reclassify the device into class I and to exempt it from the premarket notification requirements.

POINT I: FDA WILL NOT REVOKE THE CLASSIFICATION OF EXTERNAL ASSEMBLED LOWER LIMB PROSTHESIS

Initially, you petitioned FDA to publish a formal document rescinding the classification of the external assembled lower limb prosthesis (21 CFR 890.3500) because it does not exist as a finished medical device. Cit. Pet. at 1. According to the citizens petition, each part of such a prosthesis is designed, assembled, adjusted, and individually fit to each patient only after the patient has consulted with a prosthetist and the patient's exact characteristics and sizes have been established. Cit. Pet. at 2. Thus, you contend that because lower limb prostheses are not assembled, adjusted, and fitted until after the device is sold to the prosthetist, the device is only a component of a total prosthesis. As a result, you believe that such a device should be classified as an external limb orthotic component (21 CFR 890.3420) and the external assembled lower limb prosthesis classification (21 CFR 890.3500) should be eliminated. Cit. Pet. at 2.

FDA disagrees that the external assembled lower limb prosthesis does not exist as a finished medical device. In fact, FDA has found that manufacturers have distributed fully assembled lower limb prostheses in the past. As an example, a fully assembled prosthesis was marketed in several sizes so that a practitioner or patient could fit one onto an amputated leg by

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lacing it to the stump. Further, it is generally known that amputees commonly used fully assembled "peg legs" in the past. Distributors may still market these in some underdeveloped nations. Thus, a United States manufacturer could conceivably produce this device, which would be classified under 21 CFR 890.3500, for export. Moreover, while it is true that such devices may need to be adjusted and to be individually fitted to each patient, your petition incorrectly states that they need to be designed individually. Manufacturers can readily design the simpler devices of this type to fit many individuals. While these may not be the best devices of the type available, they may prove cost-effective in certain instances.

For these reasons stated above, FDA will not revoke the classification of the external assembled lower limb prosthesis (21 CFR 890.3500).

POINT II: PROSTHETISTS WHO CUSTOM FIT EXTERNAL ASSEMBLED LOWER LIMB PROSTHESES ARE NOT REQUIRED TO REGISTER

According to the petition, some FDA officials confuse the devices classified as external limb prosthetic components (21 CFR 890.3420) with devices classified as external assembled lower limb prothesis (21 CFR 890.3500). Cit. Pet. at 2. This confusion leads FDA investigators to believe that orthotic and prosthetic practitioners are manufacturing class II medical devices, and are thereby subject to the registration requirements of section 510(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(b)). Cit. Pet. at 3. To avoid such confusion, in accordance with 21 CFR 890.1(c), you requested FDA to list such a physical medical device having two or more uses in one subpart, namely 21 CFR 890.3420. Cit. Pet. at 2.

FDA agrees that confusion of some individuals has existed in the past on this issue, but disagrees that revoking the external assembled lower limb prosthesis classification (21 CFR 890.3500) will eliminate such confusion in regulating the device. The law on this point is clear. Section 510(b) of the act (21 U.S.C. 360(b)) states that an individual who owns or operates any establishment engaged in the manufacturer of devices shall register with FDA his name, places of business, and all such establishments. This section applies to both manufacturers of external limb prosthetic components (21 CFR 890.3420) and manufacturers of the external assembled lower limb prosthesis (21 CFR 890.3500). However, the law does not require registration of orthotic and prosthetic practitioners. Section 510(g) of the act (21 U.S.C. 360(g)) states that the foregoing subsections of this section, including 510(b), shall not apply to ... (2) practitioners licensed by law to prescribe or administer devices and who manufacture, prepare, propagate, compound, or process devices solely for use in the course of their professional practice. Thus, licensed prosthetists are exempt from all registration requirements regardless of the type of device they prescribe and prepare for a patient.

POINT III: FDA INTENDS TO RECLASSIFY THE DEVICE INTO CLASS I AND EXEMPT IT FROM 510(K).

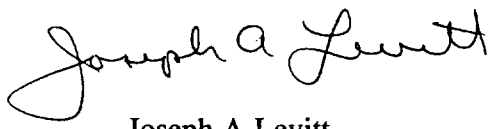
FDA intends to reclassify the external assembled lower limb prosthesis into class I and to exempt it from the 510(k) requirements. FDA believes that the remaining general controls will provide reasonable assurance of the safety and effectiveness of the device. To accomplish this end, FDA must publish a proposed rule in the **Federal Register**, provide an opportunity for public comment, and issue a final rule.

FDA is now preparing a proposed rule to reclassify and/or exempt from premarket notification a number of devices. FDA will include the external assembled lower limb prosthesis in this proposal. If the comments do not persuade FDA otherwise, FDA will finalize this rule as soon after the end of the comment period as resources permit.

CONCLUSION

In conclusion, FDA will not revoke the classification of the external assembled lower limb prosthesis because such a device does if fact exist as a finished medical device. Moreover, FDA will not list the external assembled lower limb prosthesis (21 CFR 890.3500) under external limb prosthetic components (21 CFR 890.3420) in order to eliminate any potential confusion because prosthetists who custom fit external assembled lower limb prostheses are already exempt from all registration requirements. See section 510(g)(2) of the act (21 U.S.C. 360(g)(2)). As stated above, however, FDA does intend to propose to reclassify the external assembled lower limb prosthesis into class I and to exempt it from the premarket notification requirements, as requested in your letter dated February 27, 1996.

Sincerely yours,



Joseph A Levitt
Deputy Director for
Regulations and Policy
Center for Devices and
Radiological Health

1 Enclosure